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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,254	10/14/2003	Nathalie Jongen	1/1400	4012
<div>28518      7590      02/05/2008</div> <div>MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY RD P. O. BOX 368 RIDGEFIELD, CT 06877-0368</div>				
			<div>EXAMINER</div> <div>MAEWALL, SNIGDHA</div>	
			<div>ART UNIT</div> <div>1612</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>02/05/2008</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/685,254

Applicant(s)

JONGEN ET AL.

Examiner

Snigdha Maewall

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Summary***

1. Receipt of Applicant's Arguments/Remarks and amended claims filed on 10/08/2007 is acknowledged.

Claims 1-10 have been cancelled, claim 11 has been amended and new claim 12 has been added in this application. Accordingly claims **11-12** are pending in the prosecution

### **Request for Continued Examination**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/06/2007 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 11-12 are rejected under 35 U.S.C. 102(e) as being anticipated Batycky et al. (US 2003/0180283 A1).

Batycky discloses method and apparatus for producing dry particles. The reference discloses that dry powder compositions are for pulmonary drug delivery. The dry particles of the prior art correlates with the enhanced delivery to the pulmonary system. Batycky further discloses that the aerodynamic diameter that is between about 1 and 3 microns is well suited for delivery to the alveoli or deep lung (see paragraph [0007]) on page 1). On paragraph [0046], Batycky et al. further describe the preferred dry particles are directed to inhalable salmeterol and Ipratropium compositions. (incorporated by reference see page 3).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO02/089942 A1 (herein onwards ('942)).

('942) discloses a process of making an inhalable medicament as follows: Small crystals are made by mixing a solution of a desired substance with an anti-solvent in a fluidic vortex mixer in which the residence time is less than 1 s, for example 10 ms. The liquid within the fluidic vortex mixer (12) is subjected to high intensity ultrasound from a transducer (20, 22) in or on the wall of the mixer, or coupled to a pipe supplying liquid to the mixer. The solution very rapidly becomes supersaturated, and the ultrasound can induce a very large number of nuclei for crystal growth. Small crystals, for example less than 5 micro meters are formed that may be of a suitable size for use in inhalers (abstract and the picture as shown on front page. ('942) further discloses that crystallization apparatus of the invention may be suitable for use in crystallizing a wide variety of different compounds. Some materials for which the crystallization procedure and apparatus would be useful, in order to provide a narrow particle size distribution and so to help control bio-availability, are: analgesics such as codeine; anti-allergens such as sodium cromoglycate; antibiotics such as penicillin, cephalosporins, streptomycins, or 15 sulphonamides; antihistamines; anti-inflammatories (page 12, lines, 6-15). A tubular apparatus is depicted on pages ¼ through ¾, fig. 1. and 8. It would have been obvious to one of ordinary skilled in the art at the time the invention

was made to prepare the inhalable claimed drugs since the art teaches preparing medicaments less than 5 micrometer diameter and that crystallization apparatus of the invention may be suitable for use in crystallizing a wide variety of different compounds. A skilled artisan would have been motivated to prepare an inhalable medicament with an aerodynamic diameter of less than 20 or 5 micrometer with a reasonable expectation of success.

### ***Response to Arguments***

6. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

***Snigdha Maewall***  
***Art Unit 1612***

  
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